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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,381	01/15/2004	Raphael J. Mannino	BSZ-017	6695
959 7590 06/29/2007 LAHIVE & COCKFIELD, LLP ONE POST OFFICE SQUARE BOSTON, MA 02109-2127			EXAMINER EBRAHIM, NABILA G	
			ART UNIT 1618	PAPER NUMBER
			MAIL DATE 06/29/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/759,381	<b>Applicant(s)</b> MANNINO ET AL.	
	<b>Examiner</b> Nabila G. Ebrahim	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-38 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                      | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claim 1-20, and 29-37, drawn to one or more fragile nutrient cochleates formulation comprising fragile nutrient, a negatively charged lipid component and a multivalent cation component and method of delivering these compositions classified in class 424, subclass 450.
  - II. Claim 21-28, drawn to a method of making a fragile nutrient cochleates comprising, dissolving a negatively-charged lipid component and fragile nutrient component in an organic solvent to form a liposome and exposing the fragile nutrient liposome to multivalent cation, classified in class 427, subclass 213.3.
  - III. Claim 38, drawn to a method of treating a subject, by delivering a fragile nutrient cochleate formulation, classified in class 514, subclass 44, for example.

The inventions are distinct; each from the other because of the following reasons:

Inventions of Group II and Group I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(0)). In the instant case the fragile nutrient cochleates of Group II can be made by a materially different process such as mixing a cargo moiety and a liposome and sonicating the mixture.

Inventions of Group I and Group III are related as product and method of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the fragile nutrient cochleate can be used in a materially different process such as the delivery of a cargo moiety to cells cultured in vitro.

The inventions of Group II and Group III are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of Groups II and III comprise steps which are not required for or present in the methods of the other groups dissolving a negatively-charged lipid component and fragile

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nutrient component in an organic solvent to form a liposome and exposing the fragile nutrient liposome to multivalent cation (Group II), and administering a fragile nutrient cochleate to a subject (Group III). The end results of the methods are different: making a fragile nutrient cochleate (Group I), and treating a subject (Group III).

2. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

3. This application contains claims directed to the following patentably distinct species:

- a. fragile nutrient components (claims 8-12),
  - i. if the phytochemical is elected, Applicant is required to chose one subspecies from claim 10 (beta-carotene .. etc.)
  - ii. if the zoochemical is elected, Applicant is required to elect one subspecies from claim 12.
- b. additional cargo moiety (claim 14),
- c. one product (claims 18-20),
  - i. if the food is elected, Applicant is required to chose one subspecies from claim 18 (human foods and drinks, or animal foods)
  - ii. if claim 20 is elected, Applicant is required to elect a hair care product or a skin care product.
- d. a method of making food item, personal care product, hair care product and skin care product (26-28),

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- i. If method of making the food is elected, Applicant is required to chose one subspecies from claim 18 (human foods and drinks, or animal foods)
- ii. If the step of adding a personal care product is elected, Applicant is required to elect a hair care product or skin care product (claim 28).
- e. a method of delivering fragile nutrients to a subject (claims 30-33),
  - i. If Group I is elected, Applicant is required to elect one type of food item from claim 30 (human food and drink or animal food)
  - ii. Applicant is further required to elect a hair care product or skin care product (claim 33).
- f. the administration route (claim 34), Applicant is required to elect the proper administration route according to the type of the composition or product elected.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species and subspecies that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

4. No telephone call was made to Applicant to request an oral election to the above restriction requirement because of the complexity of the restriction requirement.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

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5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nabila Ebrahim  
6/15/07

  
MICHAEL G. HARTLEY  
SUPERVISORY PATENT EXAMINER